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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,311

12/12/2005

Meena Augustus

689290-248

4638

27162

7590

06/02/2009

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EXAMINER

KIM, YOUNG J

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

06/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/540,311

**Applicant(s)**

AUGUSTUS ET AL.

**Examiner**

Young J. Kim

**Art Unit**

1637

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-59, 65 and 66 is/are pending in the application.
- 4a) Of the above claim(s) 1-15, 19-27 and 31-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-18, 28-30, 65 and 66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 30, 2009 has been entered.

### ***Election/Restrictions***

Claims 1-15, 19-27, and 31-59 remain withdrawn as being drawn to non-elected invention without traverse.

Claims 16-18, 28-30, 65, and 66 are pending and are under prosecution herein.

### ***Preliminary Remark***

The examiner of record has been changed to Young J. Kim of Group Art Unit 1637.

All future correspondence should be addressed to the present examiner of record.

### ***Information Disclosure Statement***

As of present Office communication, there is no IDS of record.

### ***Claim Rejections - 35 USC § 112***

The rejection of claims 60-64 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on September 26, 2008 is withdrawn in view of the Amendment received on March 30, 2009, canceling the rejected claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-18, 28-30, 65 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16 and 28 are indefinite for failing to recite a final process step which agrees back with the preamble. While minor details are not required in method/process claims, at least the basic steps must be recited in a positive, active fashion. See *Ex parte Elrich*, 3 USPQ2d, p. 1011 (Bd. Pat. App. Int. 1986). For example, claims 16 and 28 are drawn to a method of identifying a cancerous cell and detecting cancer, respectively, yet the claims recite a final step determining elevated expression level of SEQ ID Number 1 or its encoded mRNA. The claims do not set forth the conditions/state when the method has been completed [i.e., needs to agree with preamble].

Amending the claims to actively recite the comparison step (with a normal cell), and actively recite the step of “concluding” the positive correlation which is sought in the claim preamble would overcome this rejection.

Claims 17, 18, 29, 30, 65, and 66 are indefinite by way of their dependency on claims 16 or 28.

### ***Claim Rejections - 35 USC § 102***

The rejection of claims 60-62, and 64 under 35 U.S.C. 102(e) as being anticipated by Dai et al. (US 2003/0224374, filed 6/14/02, of record), made in the Office Action mailed on September 26, 2008 is withdrawn in view of the Amendment received on March 30, 2009, canceling the rejected claims.

The rejection of claims 60-62, and 64 under 35 U.S.C. 102(e) as being anticipated by Mutter et al. (US 6,703,204, filed 7/27/01, of record), made in the Office Action mailed on September 26,

2008 is withdrawn in view of the Amendment received on March 30, 2009, canceling the rejected claims.

The rejection of claims 60-62 under 35 U.S.C. 102(b) as being anticipated by Aziz et al. (WO 02/086443, of record), made in the Office Action mailed on September 26, 2008 is withdrawn in view of the Amendment received on March 30, 2009, canceling the rejected claims.

***Claim Rejections - 35 USC § 103***

Prior to rejection, claims are first construed.

Claim 16 is drawn to a method of identifying a cancerous cell and claim 28 is drawn to a method of detecting cancer from a patient. Both claims obtains the sample (cell or sample from patient) and “determine[s] [the] elevated expression in said cell [or sample] of at least one gene comprising the nucleotide sequence of SEQ ID Number 1, wherein said elevated expression is increased copy number of said gene in said cell relative to that of a normal cell or increased level of mRNA encoded by said gene in said cell relative to that of a normal cell” wherein the claims recite that elevated expression level indicates that said cell or sample is cancerous.

Therefore, in an embodiment, the claims do not require the detection of SEQ ID Number 1, but rather an mRNA encoded by said SEQ ID Number 1.

“TRIP13 is found as a number of splice variants, represented by the cDNA sequences of SEQ ID NO: 1-6.” (page 13, lines 10-11)

While the instant specification discloses a protein counterpart of the said cDNA sequences, the instant specification does not correlate which SEQ ID Number (SEQ ID NO: 1-6) corresponds to which encoded protein sequences (SEQ ID NO: 7-11).

The present prior art rejection is based on the finding that a prior art discloses a protein sequence which shows 100% identity to SEQ ID Number 7 of the instant application, identifying said protein as TRIP13. Therefore, burden is shifted to Applicants to show that the mRNA encoded by SEQ ID NO: 1 does not encode an mRNA which encodes the protein of SEQ ID NO: 7.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 18, 28, 30, 65, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baak et al. (WO 02/10436 A2, issued February 7, 2002).

Baak et al. disclose sets of genes which are expressed differentially in tumor characterized as high MAI or low MAI tumors, wherein the artisans expressly contemplate a method of identifying a set of nucleic acid markers or expression products for determining cancer (page 3, lines 31-33), by determining the difference in the expression of a plurality of nucleic acid molecules or expression products in the tumor tissue sample (page 4, lines 1-4; see also claims 1, 10, and 11, and 12).

In the preferred embodiment, the artisans expressly contemplate breast cancer (page 4, line 21, see claim 12 also).

Baak et al. disclose a protein which shows 100% homology to that of SEQ ID Number 7 as shown below:

```
Query Match      100.0%; Score 2186; DB 5; Length 432;
Best Local Similarity 100.0%; Pred. No. 3.2e-195;
Matches 432; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY      1 MDEAVGDLKQALPCVAESPTVHVHVHQRGSSTAKKEDINLSVRKLLNRRNIVEFGDYTWTE 60
      |||
DB      1 MDEAVGDLKQALPCVAESPTVHVHVHQRGSSTAKKEDINLSVRKLLNRRNIVEFGDYTWTE 60
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Qy      61 FDEPFLTRNVQSVSIIDTELKVKDSQPIDLSACTVALHIFQLNEDGFSSENLEETENII 120
Db      61 FDEPFLTRNVQSVSIIDTELKVKDSQPIDLSACTVALHIFQLNEDGFSSENLEETENII 120

Qy     121 AANHWWLPAEEFFHGLMDSIVYDVEKSHLLDYVMTLLFSDKNVNSNLITWNRVVLLEGF 180
Db     121 AANHWWLPAEEFFHGLMDSIVYDVEKSHLLDYVMTLLFSDKNVNSNLITWNRVVLLEGF 180

Qy     181 PGTGKTSCLKALAQKLTIRLSSRYRYGQLIEINSHSLFSKWFSESGKLVTRMPQKIQDLI 240
Db     181 PGTGKTSCLKALAQKLTIRLSSRYRYGQLIEINSHSLFSKWFSESGKLVTRMPQKIQDLI 240

Qy     241 DOKDALVFVLIDEVESLTAARNACRAGTEPSDAIRVVNAVLTQIDQIKRHSNVVILTTSN 300
Db     241 DOKDALVFVLIDEVESLTAARNACRAGTEPSDAIRVVNAVLTQIDQIKRHSNVVILTTSN 300

Qy     301 ITEKIDVAFVDRADIKQYIGPPSAAAIKFIYLSCLLEEIMKCQIYIPRQQLITLRELEMIG 360
Db     301 ITEKIDVAFVDRADIKQYIGPPSAAAIKFIYLSCLLEEIMKCQIYIPRQQLITLRELEMIG 360

Qy     361 FIENNVSLSLLNDISRKSEGLSGRVLRKLPFLAHALYVQAPTVTIEGFLQALSLAVDK 420
Db     361 FIENNVSLSLLNDISRKSEGLSGRVLRKLPFLAHALYVQAPTVTIEGFLQALSLAVDK 420

Qy     421 QFEERKKLAAYI 432
Db     421 QFEERKKLAAYI 432

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It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Baak et al. for the purpose of determining cancer for the following reasons.

Baak et al. expressly suggest that a practitioner employ the markers disclosed by the artisans in an expression assay:

“A method of diagnosing breast cancer in a subject suspected of having breast cancer comprising: obtaining from the subject a breast tissue sample suspected of being cancerous, determining the expression of a set of nucleic acid molecules or the expression products thereof in the breast tissue samples” (claim 1), wherein the artisans also expression suggest for the method also determine the expression level of said set of nucleic acid molecules or expression product thereof, and compare the expression of the set of nucleic acid molecules or expression products thereof in the breast tissue sample suspected of being cancerous and the non-cancerous breast tissue sample.”

Thus, one of ordinary skill in the art would have been clearly motivated to compare the expression level of the protein or its encoding nucleic acid molecule (or mRNA) of Baak et al. (which is known as TRIP13<sup>1</sup>) from a sample suspected of being cancerous and from a non-cancerous cell for the explicitly suggested diagnosis of breast cancer.

While the artisans do not disclose the nucleotide of instant SEQ ID Number 1, as stated previously, instantly rejected claims embrace an embodiment wherein an mRNA encoded by SEQ ID NO: 1 is determined and not SEQ ID NO: 1 itself. Since the protein disclosed by Baak et al. is the same as the protein disclosed by the instant application (SEQ ID NO: 7), it is asserted that the nucleic acid encoding the protein (i.e., mRNA) disclosed by Baak et al. would be the same mRNA encoded by the instant SEQ ID NO: 1, absent evidence to the contrary.

With respect to determining an “overexpression” of the mRNA, since Baak et al. explicitly contemplate comparing the nucleic acid encoding their protein (which is identical to SEQ ID NO: 7) from cancerous and normal cells, such discovery would have been inherent and would have been revealed to said one of ordinary skill in the art conducting the diagnosis method.

Therefore, the invention as claimed is deemed *prima facie* obvious over the cited references.

### ***Conclusion***

Claims 17 and 29 are free of prior art as the prior art neither disclose nor suggest for a method of determining cancer in a cell or sample by determining the elevated expression of at least one gene comprising the nucleotide of SEQ ID NO: 1, wherein the elevated expression is increased copy number. Since copy number of the SEQ ID NO: 1 gene requires that the method actually look for the presence of SEQ ID NO: 1 in cell or sample for determining the copy number, and

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<sup>1</sup> While Baak et al. do not expressly state that the protein is TRIP-13, the search in the NCBI database reveals that the



since increased copy number does not necessarily result in the increase in its mRNA level, this embodiment is deemed novel and/or unobvious over the prior art.

### *Inquiries*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 9:00 a.m. to 5:30 p.m (M-F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like

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assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Young J. Kim/  
Primary Examiner  
Art Unit 1637  
6/2/2009

/YJK/